K011406 p1/2

DEC 2 7 2001

MEDTRONIC Sofamor Danek
SPINAL MESH™ System 510(k) Summary
October 2001

I. **Company:**

Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Product Name:** SPINAL MESH™ System
Classification: MQP

III. **Description:** The Medtronic Sofamor Danek SPINAL MESH™ device is a cylindrically shaped implantable device with open ends and a hollow core throughout its longitudinal axis. Pyramid shaped openings are built into the wall of the device. These openings and the hollow core allow grafting material to be placed inside the device to help achieve a solid fusion. The contoured ends of the SPINAL MESH™ device serve to grip the superior and inferior end plates, thus allowing expulsion resistance.

The device is made from commercially pure titanium or titanium alloy conforming to such voluntary standards as ASTM F67 and ASTM F136 or the ISO equivalents 5832-2 and 5832-3, and is available in various sizes to match the patients' anatomical requirements.

The SPINAL MESH™ device is intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine. These systems include the ZPLATE-II™ Anterior Fixation System, the CD HORIZON® Spinal System, the TSRH® Spinal System, the DYNALOK™ CLASSIC Spinal System, and the Laurain DeWald Anterior Fixation System.

IV. **Indications for Use:** The Medtronic Sofamor Danek SPINAL MESH™ System is for use in the thoracolumbar spine (T1 to L5) to replace and restore the height of a diseased or damaged vertebral body caused by tumor and/or fracture. The SPINAL MESH™ device is intended to be used with supplemental fixation. Allograft or autograft material may be used at the surgeon's discretion.

V. **Substantial Equivalence:** The Medtronic Sofamor Danek SPINAL MESH™ System was demonstrated to be substantially equivalent to similar previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2001

Richard W. Treharne, Ph.D.
Senior Vice President, Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K011406
Trade/Device Name: SPINAL MESH™ System
Regulatory Number: 21CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: MQP
Dated: October 18, 2001
Received: October 19, 2001

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011406

Device Name: SPINAL MESH™ System

Indications for Use:

The Medtronic Sofamor Danek SPINAL MESH™ System is for use in the thoracolumbar spine (T1 to L5) to replace and restore the height of a diseased or damaged vertebral body caused by tumor and/or fracture. The SPINAL MESH™ device is intended to be used with supplemental fixation. Allograft or autograft material may be used at the surgeon's discretion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011406